



PATENT  
Attorney Docket No.: JHU1630-1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants:	Sukumar et al.	Art Unit:	1634
Serial No.:	10/059,579	Examiner	J. Souaya
Filed:	January 28, 2002	Conf. No.:	7778
Title:	ABERRANTLY METHYLATED GENES AS MARKERS OF BREAST MALIGNANCY		

**Mail Stop NON-FEE AMENDMENT**

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION OF APPLICANTS UNDER 37 C.F.R. §1.131**

Sir:

I, Saraswati Sukumar, co-inventor of the above-identified patent application do hereby declare and state that:

I am a co-inventor of the above-identified patent application, which was conceived and reduced to practice in the United States.

I am familiar with the contents of the above-identified patent application.

I have reviewed the Sirchia et al. reference (Oncogene (2000) 19:1556-1563) and am aware that it was published in 2000, which is more than one year prior to the January 28, 2002, filing date of the above-identified patent application.

I am also aware that the Examiner has asserted that the Sirchia et al. reference allegedly anticipates the claims of the above-identified patent application under 35 U.S.C. § 102.

It is respectfully submitted that the claimed invention was conceived in the United States and reduced to practice prior to the 2000 publication date of the Sirchia et al. reference, as supported by the evidence which follows:

At the time the present invention was conceived and reduced to actual practice, I was the leader of the research team that performed the experiments set forth in the Examples of the present application and in U.S. application Serial No. 09/771,357, filed January 26, 2001, from which application the present invention claims priority under 35 U.S.C. §120. These experiments were completed in laboratories of The Johns Hopkins University School of Medicine in Baltimore, Maryland prior to the publication date of the Sirchia et al. reference.

At the time the present invention was conceived and reduced to practice, Nicoletta Sacchi was the leader of the research team that authored the Sirchia et al. article, and I am one of the co-authors of the Sirchia et al. reference. The research described in the Sirchia et al. reference was conceived by the co-inventors of the priority application and was carried out under her direction.

Nicoletta Sacchi, who is named as one of the co-authors of the Sirchia et al. reference, is one of the co-inventors of the present application and contributed to conception of the invention described in the priority application. By contrast, Silvia M. Sirchia, Anne T. Ferguson, Elena Sironi, Smitha Subramanyan and Rosaria Orlandi, who are named as co-authors of the Sirchia et al. reference, contributed to the research effort that led to the Sirchia reference but did not contribute to conception of the invention as described in the present application or as described in the priority application.

Thus, I maintain that the subject matter contained in the Sirchia et al. reference that is relied upon in the rejection of claims 1-2, 4, 6-31 and 34-41 of the present application for alleged anticipation was conceived and reduced to practice by the co-inventors of the present application prior to the date of publication of the Sirchia et al. reference. Further, the co-inventors were diligent from the time of conception of the invention until the time of filing the above-identified priority application.

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4. I further declare that all statements made herein of knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

9/29/03  
Date

Saraswati Sukumar  
Saraswati Sukumar



DECLARATION FOR PATENT APPLICATION

As a below-named inventor, I hereby declare that:

My residence, post office address and citizenship is as stated below next to my name.

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled, **ABERRANTLY METHYLATED GENES AS MARKERS OF BREAST MALIGNANCY**, the specification of which:

\_\_\_\_\_ is attached hereto.

**X** was filed on **January 28, 2002** (Attorney Docket No.: **JHU1630-1**) as U.S. Application Serial No. 10/059,579.

I hereby authorize and request insertion of the application serial number of the Application when officially known.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability of the subject matter of the Application as defined in Title 37, Code of Federal Regulations ("C.F.R."), § 1.56.

With respect to the Application, I hereby claim the benefit under 35 U.S.C. Section 120 of any United States non provisional application(s) listed below:

<u>09/771,357</u>	<u>January 26, 2001</u>
(Application Serial No.)	(Filing Date)
<u>                    </u>	<u>                    </u>
(Application Serial No.)	(Filing Date)
<u>                    </u>	<u>                    </u>
(Application Serial No.)	(Filing Date)

With respect to the Application, I hereby claim the benefit under 35 U.S.C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of the application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability of the subject matter of the Application as defined in Title 37, C.F.R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of the Application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor: Saraswati Sukumar

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Date: \_\_\_\_\_

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Full name of second inventor: Ella Evron

Inventor's signature: \_\_\_\_\_

Date: \_\_\_\_\_

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Full name of third inventor: William C. Dooley

Inventor's signature: \_\_\_\_\_

Date: \_\_\_\_\_

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Citizenship: United States

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Full name of fourth inventor: Nicoletta Sacchi

Inventor's signature: \_\_\_\_\_

Date: \_\_\_\_\_

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Full name of fifth inventor: Nancy Davidson

Inventor's signature: \_\_\_\_\_

Date: \_\_\_\_\_

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Full name of fifth inventor: Mary Jo Fackler

Inventor's signature: \_\_\_\_\_

Date: \_\_\_\_\_

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